

REMARKS

Claims 1-51 are in the case and presented for reconsideration. Claims 1, 12, 16, 30, 35, 42 and 47 have been amended. No new matter has been added.

Claims 12-51 have been rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. Accordingly, the claims as amended above are believed to have overcome this rejection.

Claims 1-3, 7, 12, 13, 15-18, 22, 32-37, 39-45 and 47-50 have been rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 5,718,241 (Ben-Haim et al.). With respect to this rejection the Examiner has stated:

Ben-Haim et al. disclose a method and apparatus to treat arrhythmias with ablation using one or more catheters (abstract). The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (column 11, lines 28-35). The electromagnetic location system in the tip of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (column 11, lines 49-59). In figure 16, a tip electrode (105) and additional electrodes (106), read as an array of non-contact electrodes, are disclosed. The receiving antennas are located near the distal tip of the catheter (column 12, lines 41-47).

With respect to considering patentability of the claims under 35 U.S.C. § 103 (a), the Examiner is correct in the presumption that the subject matter of the claims was commonly owned at the time of the inventions covered therein.

Claims 4-6, 14, 19-21, 26-31, 38, 46 and 51 have been rejected under 35 U.S.C. § 103 (a) as being unpatentable over Ben-Haim et al. in view of U.S. Patent 6,104,944 (Martinelli). With respect to this rejection, the Examiner has stated:

As discussed in paragraph 2 of this action, Ben-Haim et al. disclose the claimed invention except for providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array.

Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nn), read as location sensors, between multiple virtually navigable electrode elements (E1-En), read as an array of non-contact electrodes (column 4, line 66 —column 5, line 8 and column 5, lines 24-33) to define the position of electrodes in a domain such as a chamber of the heart (column 4, lines 63-66). Martinelli teaches the use of electromagnetic field sensors as the navigated electrode elements to provide navigational location information (column 6, lines 18-32). These navigated electrode elements provide orientation data and position coordinate data, read as the six degrees of location information (column 6, lines 54-64 and column 8, lines 29-65), to establish the location of the virtually navigated electrodes and enable accurate mapping of the heart.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array as taught by Martinelli to enable accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated.

Claims 8, 11, and 23 have been rejected under 35 U.S.C. § 103 (a) as being unpatentable over Ben-Haim in view of U.S. Patent 6,171,306 (Swanson et al.). With respect to this rejection, the Examiner has stated:

As discussed in paragraph 2 of this action, Ben-Haim discloses the claimed invention except for the distal tip contact electrode being a bipolar electrode. Swanson et al. disclose an ablation catheter and teach that it is known to use a bipolar distal tip electrode to ablate the cardiac tissue (figure 5, and column 7, lines 11-14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, with a bipolar distal tip electrode as taught by Swanson et al. to utilize the electrodes in the device, the tip and the array electrodes, to ablate the tissue, eliminating the need for the addition of an external indifferent electrode (column 7, lines 17-20). Utilizing a bipolar configuration also provides a more targeted ablating stimulus enabling more precise ablation.

Claims 9, 10, 24 and 25 have been rejected under 35 U.S.C. § 103 (a) as being unpatentable over Ben-Haim in view of U.S. Patent 5,311,866 (Kagen et al.). With respect to this rejection, the Examiner has stated:

As discussed in paragraph 2 of this action, Ben-Haim discloses the claimed invention except for the electrode array comprising about twelve to about thirty-two or about sixteen to about twenty-four electrodes. Kagen et al. disclose an heart mapping catheter and teach that it is known to use an array of between twenty-four and sixty-four electrodes to map the electrical activity of the heart (column 3, lines 25-29). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, with an array of about twenty-four electrodes as taught by Kagen et al. to enable sufficient contact between the electrode array and the cardiac tissue to gain a clear understanding of the electrical activity of the heart so appropriate ablation treatment could be performed.

With respect to the prior art references cited by the Examiner above, the Applicant would like to point out that Ben-Haim et al. is directed to an apparatus and method for treating cardiac arrhythmias with no discrete target. As pointed out by The Examiner, the apparatus includes a catheter having a tip electrode 105 and "may have additional electrodes 106" such as the electrode 106 as shown in Fig. 16. It is important to note that the electrode 106 in the embodiment of Fig. 16 is directed to a ring electrode.

Additionally, with respect to the Martinelli reference, Martinelli discloses a system and method for navigating a multiple electrode catheter including navigated electrode elements N_1 - N_n distributed along an end length 21 of a catheter 20. Column 5, lines 24-27. As described by Martinelli, virtually navigable electrode elements E_1 - E_n are positioned "between pairs of the navigated electrode elements N_1 - N_n ." Column 5, lines 27-29. It is important to note that Martinelli neither describes, suggests or infers the use of a contact electrode at the distal tip of its device. Additionally, it is also important to note that the virtually navigable electrode elements E_1 - E_n as shown in the embodiments of Figs. 3a, 3b, and Fig. 8 are ring electrodes.

Swanson et al. describes systems and methods for forming large lesions in body tissue using curvilinear electrode elements. The Swanson et al. device includes an ablating element 10 for making lesions within the heart which is carried at the distal end of a catheter body 12 of an ablating probe 14. Column 5, lines 26-30. As taught by Swanson et al. in one embodiment, the ablating element includes multiple, generally rigid electrode elements 30. Column 6, lines 14-18.

Additionally, in another embodiment (Fig. 5) the Swanson et al. device includes one or more conventional sensing ring electrodes 40 spaced from an ablating ring electrode 36. Column 6, lines 48-51.

Also, Kagan et al. discloses a heart mapping catheter having a deformable lead-body 14 made of a braid 15 of insulating wires (shown as wire 33, wire 34, wire 35 and wire 36). Column 3, lines 15-17. As described in Kagan et al., "each of the several wires in the braid 15 may potentially used to form an electrode site" and "preferably all of the typically twenty-four to sixty-four wires in the braid 15 are used to form electrode sites." Column 3, lines 25-29.

Turning now to the present invention, the Applicant has amended independent claims 1, 12, 16, 35, 42 and 47 in order to more particularly point out the claimed invention. For instance, amended claim 1 of the present invention is a catheter comprising a body having a proximal end and a distal end wherein the distal end has a distal tip; a contact electrode at the distal tip; an array of non-contact electrodes on the distal tip of the body wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body; and at least one location sensor on the distal end of the body.

Amended claim 12 has been amended in order to particularly point out a catheter comprising a body having a proximal end and a distal end wherein the distal end has a distal tip; an array of non-contact electrodes on the distal end of the body wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body; and at least one location sensor proximate to the distal tip.

Claim 16 has been amended in order to particularly point out a method for generating an electrical map of a chamber of a heart wherein the map depicts an electrical characteristic of the chamber as a function of chamber geometry wherein the method comprises the steps of: providing a catheter comprising a body having a proximal end and a distal end wherein the distal end has a distal tip, a contact electrode at the distal tip, an array of non-contact electrodes on the distal end of the body, wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body, and at least

one location sensor on the distal end of the body; advancing the catheter into the chamber of the heart; contacting a wall of the chamber of the heart with the contact electrode at a plurality of contact points; acquiring electrical information and location information from each of the electrodes and the at least one location sensor respectively wherein the acquisition takes place over at least one cardiac cycle while the contact electrode is in contact with each of the contact points; and generating an electrical map of the heart chamber from the acquired location and electrical information.

Claim 35 has been amended in order to more particularly point out a method for generating an electrical map of a chamber of a heart wherein the map depicts an electrical characteristic of the chamber as a function of chamber geometry wherein the method comprises the steps of: providing a catheter comprising a body having a proximal end and a distal end wherein the distal end has a distal tip, an array of non-contact electrodes on the distal end of the body wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body, and at least one location sensor proximate to the catheter distal tip; advancing catheter into the chamber of the heart; contacting a wall of the chamber of the heart with the catheter distal tip at a plurality of contact points; acquiring electrical information and location information from each of the electrodes and location sensors respectively wherein the acquisition takes place over at least one cardiac cycle while the catheter distal tip is in contact with each of the contact points; and generating an electrical map of the heart chamber from the acquired location and electrical information.

Claim 42 has been amended in order to more particularly point out an apparatus for generating an electrical map of a chamber of a heart wherein the map depicts and electrical characteristic of the chamber as a function of chamber geometry wherein the apparatus comprises: a catheter including a body having a proximal end and a distal end wherein the distal end has a distal tip, a contact electrode at the distal tip and an array of non-contact electrodes on the distal end of the body wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body, and at least one location sensor on the distal end of the body, wherein the catheter is adapted to contacting a wall of the chamber of the heart with the contact electrode at a plurality of contact points; and a

signal processor operatively connected to the catheter for acquiring electrical information and location information from each of the electrodes and location sensors respectively over at least one cardiac cycle while the contact electrode is in contact with each of the contact points wherein the signal processor also generates an electrical map of the heart chamber from the acquired location and electrical information.

Claim 47 has been amended in order to more particularly point out an apparatus for generating an electrical map of the chamber of the heart wherein the map depicts an electrical characteristic of the chamber as a function of chamber geometry wherein the apparatus comprises: a catheter including a body having a proximal end and a distal end wherein the distal end has a distal tip, an array of non-contact electrodes on the distal end of the body, wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body, and at least one location sensor proximate to the catheter distal tip wherein the catheter is adapted to contacting a wall of the chamber of the heart with the catheter distal tip at a plurality of contact points; and a signal processor for acquiring electrical information and location information from each of the electrodes and location sensors respectively over at least one cardiac cycle while the catheter distal tip is in contact with each of the contact points and wherein the signal processor generates an electrical map of the heart chamber from the acquired location and electrical information.

The Applicant would like to emphasize that none of the cited prior art references outlined above describe, suggest or infer a catheter having the novel elements as claimed in independent claims 1 (Amended) and 12 (Amended) of the present invention; or a novel method having the novel method steps as claimed in claims 16 (Amended) and 35 (Amended) of the present invention; or a novel apparatus comprising a novel catheter and signal processor and the novel elements therefor as claimed in claims 42 (Amended) and 47 (Amended) of the present invention. Particularly, none of the cited prior art references include a catheter having a body with an array of non-contact electrodes on the distal end of the body wherein the array has a proximal end and a distal end and wherein the non-contact electrodes are linearly arranged along a longitudinal access of the body and at least one location sensor on the distal end of the body as

provided for by amended claims 1, 12, 16, 35, 42 and 47 of the present invention. Moreover, none of the cited prior art references include these novel features along with a contact electrode at the distal tip of the catheter body such as claimed in amended claims 1, 16 and 42 of the present invention. Additionally, none of the cited prior art references describe, suggest or infer these novel elements as outlined above in conjunction with the other novel steps of the method in accordance with the present invention of amended claims 16 and 35 or the novel elements of the signal processor of amended claims 42 and 47 of the present invention.

It is important to note that all of the cited prior art references outlined above describe catheters having distal ends of a "continuous electrode geometry" which are in the form of either ring electrodes such as described in Ben-Haim et al., Martinelli and Swanson et al. or wire braids such as described in Kagan et al. Accordingly, these type of devices having electrodes of a continuous electrode geometry provide signals that represent average electrical activity in the heart chamber and encounter difficulties in determining local electrical activity. The downside to these catheter distal end geometries as described in the cited prior art references is clearly addressed in the Applicant's Specification at page 14, lines 17-23, where it is stated:

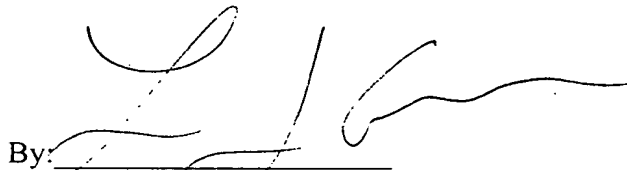
In contrast, non-contact electrodes that are continuous about the catheter circumference would provide signals that would represent average electrical activity in the heart chamber, from which it would be more difficult to determine local electrical activity. Ring electrodes are an example of a continuous electrode geometry that completely encircles the catheter circumference, and, as such, are not preferred for use as the non-contact electrodes in the practice of the invention.

Accordingly, the claimed present invention as amended is patentably distinct and non-obvious over these cited prior art references. Moreover, dependent claims 2-11 depend either directly or indirectly from amended claim 1, dependent claims 13-15 depend either directly or indirectly from independent claim 12, dependent claims 17-34 depend either directly or indirectly from amended claim 16, claims 36-41 depend either directly or indirectly from amended claim 35, claims 43-46 depend either directly or indirectly from amended claim 42, and dependent claims 48-51 depend either directly or indirectly from amended claim 47 wherein all of these dependent claims further patentably distinguish the claimed invention over the cited prior art. Accordingly, favorable action is respectfully requested.

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Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 1. (Amended) A catheter comprising:

a body having a proximal end and a distal end, said distal end having a distal tip;

a contact electrode at said distal tip;

an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and

at least one location sensor on said distal end of said body.

~~each provide six degrees of location information.~~

Claim 12. (Amended) A catheter comprising:

a body having a proximal end and a distal end, said distal end having a distal tip;

an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and

at least one location sensor proximate to said [catheter] distal tip.

Claim 16 (Amended) A method for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said method comprising the steps of:

- a) providing a catheter comprising a body having a proximal end and a distal end, said distal end having a distal tip; a contact electrode at said distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor on said distal end of said body;
- b) advancing said catheter into said chamber of said heart;
- c) contacting [the] a wall of said chamber of said heart with said contact electrode at a plurality of contact points;

- d) acquiring electrical information and location information from each of said electrodes and said at least one location sensor, respectively, said acquisition taking place over at least one cardiac cycle while said contact electrode is in contact with each of said contact points; and
- e) generating an electrical map of said heart chamber from said acquired location and electrical information.

Claim 30. (Amended) The method of claim 29 [wherein said] including determining electrical characteristics intermediate said contact points [are derived] from the electrical information acquired from said non-contact electrodes.

Claim 35. (Amended) A method for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said method comprising the steps of:

- a) providing a catheter comprising a body having a proximal end and a distal end, said distal end having a distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor proximate to said catheter distal tip;
- b) advancing said catheter into said chamber of said heart;
- c) contacting [the] a wall of said chamber of said heart with said catheter distal tip at a plurality of contact points;
- d) acquiring electrical information and location information from each of said electrodes and location sensors, respectively, said acquisition taking place over at least one cardiac cycle while said catheter distal tip is in contact with each of said contact points; and
- e) generating an electrical map of said heart chamber from said acquired location and electrical information.

Claim 42. (Amended) Apparatus for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said apparatus comprising:

a catheter including a body having a proximal end and a distal end, said distal end having a distal tip; a contact electrode at said distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor on said distal end of said body; said catheter being adapted to contacting [the] a wall of said chamber of said heart with said contact electrode at a plurality of contact points; and a signal processor operatively connected to said catheter for acquiring electrical information and location information from each of said electrodes and location sensors, respectively, over at least one cardiac cycle while said contact electrode is in contact with each of said contact points, said signal processor also generating an electrical map of said heart chamber from said acquired location and electrical information.

Claim 47. (Amended) Apparatus for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said apparatus comprising:

a catheter including a body having a proximal end and a distal end, said distal end having a distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor proximate to said catheter distal tip; said catheter being adapted to contacting [the] a wall of said chamber of said heart with said catheter distal tip at a plurality of contact points; and a signal processor for acquiring electrical information and location information from each of said electrodes and location sensors, respectively, over at least one cardiac cycle while said catheter distal tip is in contact with each of said contact points; said signal processor also generating an electrical map of said heart chamber from said acquired location and electrical information.